

I. The Office Action

The May 20, 2003 non-final office action (the "Office Action") in this application:

1. requested a copy of Form 210 from related application PCT/US94/14717
2. rejected claims 23 and 27-31 under 35 U.S.C. §112, second paragraph;
3. rejected claims 21-25 and 27-28 under 35 U.S.C. §102(b) as being anticipated by Harris et al. (U.S. patent 5,482,931);
4. rejected claims 21-31 under 35 U.S.C. §103(a) as being unpatentable over Johnson in view of Elston, further in view of Borodic, or Schantz or Wilson.
5. rejected claims 21-31 under 35 U.S.C. §103(a) as being unpatentable over of Elston in view of Borodic, or Schantz or Wilson, further in view of Adenis.
6. rejected claims 21-31 under 35 U.S.C. §103(a) as being unpatentable over Adenis in view of Borodic, or Schantz or Wilson, further in view of Elston.
7. rejected claims 21-31 under the judicially created doctrine of obviousness-type double patenting over claims 1-8 of U.S. Patent No.. 6,290,961 in view of Elston and Adenis, further in view of Borodic, or Schantz or Wilson.

Applicant's respond to the Office Action as follows.

II. Requested Copy of Form 210

The Office Action requested a copy of Form 210 (the International Search Report) from related application PCT/US94/14717. Enclosed is a copy of the requested Form 210, as published in related application PCT/US94/14717 on October 19, 1995.

Although not requested, please also find enclosed for the Examiner's convenience, copies of the 5 art items cited on the Form 210. The Jenzer reference has been previously considered by the Examiner. The other four references disclose various uses of a botulinum toxin type A.

III. Rejection of Claims 23 and 27-31 under 35 U.S.C. §112(2)

The Office Action rejected claims 23 and 27-31 under 35 U.S.C. §112, second paragraph, based upon use of the word about in these claims.

Claims 23 and 27-30 have been cancelled and the word about has been deleted from claim 31. Therefore the rejection should be withdrawn.

IV. Rejection of Claims 21-25 and 27-28 under 35 U.S.C. §102(b)

The Office Action rejected claims 21-25 and 27-28 under 35 U.S.C. §102(b) as being anticipated by Harris et al. (U.S. patent no. 5,482,931).

Harris et al (U.S. patent no. 5,482,931) discloses stabilized aqueous pharmaceutical compositions of particular peptides and does not appear to be relevant with regard to the claims of this application. The text of this rejection cited Johnson et al., and it is therefore assumed that claims 21-25 and 27-28 are rejected over Johnson et al (U.S. patent no. 5,696,077).

Applicant's hereby cancel claims 21-30 without prejudice to further prosecution at a later date.

Claim 31 was not rejected. Hence, the rejection should be withdrawn.

V. Rejection of Claims 21-31 under 35 U.S.C. §103(a)

The Office Action rejected claims 21-31 under 35 U.S.C. §103(a) as being unpatentable over Johnson in view of Elston, further in view of Borodic, or Schantz or Wilson. Only claim 31 remains pending. Respectfully, the rejection is in error and should be withdrawn with regard to claim 31.

Enclosed with this application as filed, was a copy of the February 8, 2001 Brin declaration. Dr. Brin is by "training and experience...an expert in the therapeutic use of the botulinum toxins..." (paragraph 3 of the Brin dec). The Brin declaration also states that "...prior to December 28, 1993, it would have been foolhardy and dangerous to use botulinum toxin type B to treat patients...in light of the complete lack of clinical experience with the type B toxin as of that date."

It was discovery of the inventors of this application that botulinum toxin type B could be used to treat certain muscle conditions, such as strabismus.

The statements in the Brin declaration countervail and overcome the allusions in, or a construal of, Borodic, Schantz and Wilson regarding any potential clinical use of a botulinum toxin type B. Thus, the combination Johnson and Elston and Borodic, the combination of Johnson and Elston and Schantz, and the combination of Johnson and Elston and Wilson cannot teach or suggest the claimed invention.

Additionally, Wilson (1982) discusses the multiple, widespread and diverse symptoms of type B botulism. Botulism occurs upon inadvertent intoxication (systemic poisoning) of a person with a large amount of a botulinum toxin. Claim 31 in this application is limited to the local administration ("by intramuscular injection or by subcutaneous injection") of a minute amount of a type B botulinum toxin. Thus, a combination of Johnson, Elston and Wilson cannot teach or suggest the claimed invention.

Furthermore, Borodic's study was in rabbits, not in humans. It is well known that there is "...species specificity of the various (botulinum) toxin types..." (page 76 of Moyer, E., et al, *Botulinum toxin type B: experimental and clinical evidence*, chapter 6 (pages 71-85) of Jankovic, J., et al., *Therapy with botulinum toxin*, Marcel Dekker, Inc. (1994) (copy enclosed). Hence, a histological study in rabbits does not indicate a clinical efficacy in humans. Thus, any art combination with the Borodic reference cannot teach or suggest the claimed invention.

For these reasons the rejection should be withdrawn.

VI. Rejection of Claims 21-31 under 35 U.S.C. §103(a)

The Office Action rejected claims 21-31 under 35 U.S.C. §103(a) as being unpatentable over Elston in view of Borodic, or Schantz or Wilson, further in view of Adenis. Respectfully, the rejection is in error and should be withdrawn with regard to claim 31.

Enclosed with this application as filed, was a copy of the February 8, 2001 Brin declaration. Dr. Brin is by "training and experience...an expert in the therapeutic use of the botulinum toxins..." (paragraph 3 of the Brin dec). The Brin declaration also states that "...prior to December 28, 1993, it would have been foolhardy and dangerous to use botulinum toxin type B to treat patients...in light of the complete lack of clinical experience with the type B toxin as of that date."

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The statements in the Brin declaration countervail and overcome the allusions in or a construal of Borodic, Schantz and Wilson regarding any potential clinical use of a botulinum toxin type B. Thus, none of the art combinations teach or suggest the claimed invention.

Additionally, Wilson (1982) discusses the multiple, widespread and diverse symptoms of type B botulism. Botulism occurs upon inadvertent intoxication (systemic poisoning) of a person with a large amount of a botulinum toxin. Claim 31 in this application is limited to the local administration ("intramuscular or subcutaneous administration") of a minute amount of a type B botulinum toxin. Thus, due to distinctions between botulism and a therapeutic use of a botulinum toxin, any art combination with the Wilson reference cannot teach or suggest the claimed invention.

Furthermore, Borodic's study was in rabbits, not in humans. It is well known that there is "...species specificity of the various (botulinum) toxin types..." (page 76 of Moyer, E., et al, *Botulinum toxin type B: experimental and clinical evidence*, chapter 6 (pages 71-85) of Jankovic, J., et al., *Therapy with botulinum toxin*, Marcel Dekker, Inc. (1994) (copy enclosed). Hence, a histological study in rabbits does not indicate a clinical efficacy in humans. Thus, any art combination with the Borodic reference cannot teach or suggest the claimed invention.

For these reasons the rejection should be withdrawn.

VII. Rejection of Claims 21-31 under 35 U.S.C. §103(a)

The Office Action rejected claims 21-31 under 35 U.S.C. §103(a) as being unpatentable over Adenis in view of Borodic, or Schantz or Wilson, further in view of Elston. Only claim 31 remains pending. Respectfully, the rejection is in error and should be withdrawn with regard to claim 31.

Enclosed with this application as filed, was a copy of the February 8, 2001 Brin declaration. Dr. Brin is by "training and experience...an expert in the therapeutic use of the botulinum toxins..." (paragraph 3 of the Brin declaration). The Brin declaration also states that "...prior to December 28, 1993, it would have been foolhardy and dangerous to use botulinum toxin type B to treat patients...in light of the complete lack of clinical experience with the type B toxin as of that date."

It was discovery of the inventors of this application that botulinum toxin type B could be used to treat certain muscle conditions, such as strabismus.

The statements in the Brin declaration countervail and overcome the allusions in, or a construal of, Borodic, Schantz and Wilson regarding any potential clinical use of a botulinum toxin type B. Thus, none of the art combinations teach or suggest the claimed invention.

Additionally, Wilson (1982) discusses the multiple, widespread and diverse symptoms of type B botulism. Botulism occurs upon inadvertent intoxication (systemic poisoning) of a person with a large amount of a botulinum toxin. Claim 31 in this application is limited to the local administration ("intramuscular or subcutaneous administration") of a minute amount of a type B botulinum toxin. Thus, due to distinctions between botulism and a therapeutic use of a botulinum toxin, any art combination with the Wilson reference cannot teach or suggest the claimed invention.

Furthermore, Borodic's study was in rabbits, not in humans. It is well known that there is "...species specificity of the various (botulinum) toxin types..." (page 76 of Moyer, E., et al, *Botulinum toxin type B: experimental and clinical evidence*, chapter 6 (pages 71-85) of Jankovic, J., et al., *Therapy with botulinum toxin*, Marcel Dekker, Inc. (1994) (copy enclosed). Hence, a histological study in rabbits does not indicate a clinical efficacy in humans. Thus, any art combination with the Borodic reference cannot teach or suggest the claimed invention.

For these reasons the rejection should be withdrawn.

VIII. Rejection of Claims 21-31 under the judicially created doctrine of obviousness-type double patenting

The Office Action rejected claims 21-31 under the judicially created doctrine of obviousness-type double patenting over claims 1-8 of U.S. patent no.. 6,290,961 in view of Elston and Adenis, further in view of Borodic, or Schantz or Wilson.


Enclosed is an executed terminal disclaimer. Hence, the rejection should be withdrawn.

IX. Conclusion

All issues raised by the Office Action have been addressed. Reexamination, reconsideration and allowance of claim 31 is requested.

Respectfully Submitted,

Date: September 30, 2003


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I hereby certify that this Response to Office Action and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date September 30, 2003 in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV295682832US addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Susan Bartholomew
Name of person mailing paper


Signature of person signing paper

Date: September 30, 2003